

**Appl. No.** : 10/628,880  
**Filed** : July 28, 2003

#### **AMENDMENTS TO THE DRAWINGS**

The attached sheets of drawings include changes to Figures 4-12. These sheets replace the original sheets including Figures 4-12. In Figures 4-12, references "D" and "AZ" have been added to point out examples of a distal end and an anchor zone shown, described, and claimed in the application as filed. Also, in Figure 6, incorrectly placed reference number "19" has been deleted.

**Appl. No.** : 10/628,880  
**Filed** : July 28, 2003

### **REMARKS**

This Amendment is in response to the Office Action mailed June 15, 2006 in the above captioned application.

In the Office Action, Claims 27-34 were rejected over the prior art as discussed below.

In this Amendment, Claims 1-26 and 35-77 have been cancelled. Claim 27 has been amended. Claims 78-91 have been added. Claims 27-34 and 78-91 stand pending following entry of the foregoing amendments.

#### Objection Under 37 CFR § 1.83(a)

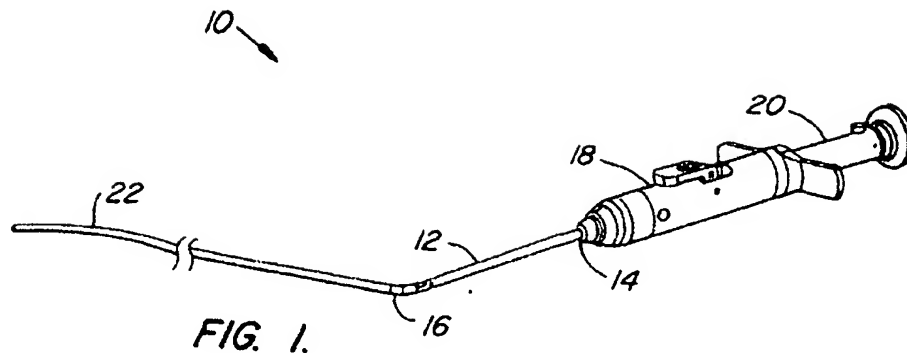
The drawings are objected to under 37 CFR § 1.83(a) because the claims recite “anchor zone” while the drawings do not have a corresponding reference number. Figures 4-12 have been amended herein to include the references D and “AZ” in connection with examples of distal ends and anchor zones, which were shown and described but not specifically labeled in the application as filed. No new matter has been added. Applicants respectfully request that the objection to the drawings be withdrawn.

#### Rejections of Claims 27-31 Based on Modesitt

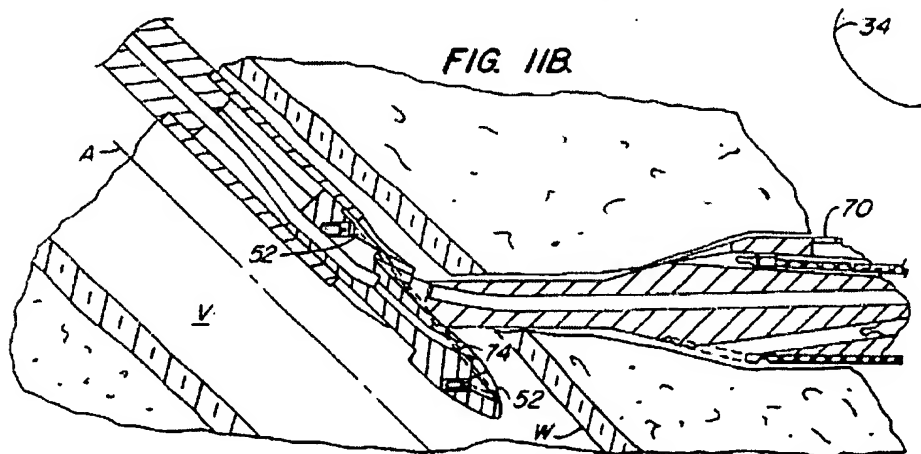
Claims 27 and 31 have been rejected as anticipated under § 102 based on Modesitt (U.S. Patent No. 6,136,010). Additionally, Claims 28-30 have been rejected as obvious under § 103 based on Modesitt alone. Applicants disagree with the characterization of Modesitt and with these rejections. However, to expedite allowance Claim 27 has been amended as set forth above. Amended Claim 27 and the claims that depend therefrom are allowable over Modesitt, as discussed further below.

#### **Modesitt**

Modesitt is directed to a vessel closure device 10 for closing vessel wall punctures. Figures 1 and 11B show that the device 10 includes an articulatable foot 24 near a distal end 16 of a shaft 12 that is inserted through a vessel penetration and actuated so that the foot 24 extends along an axis of the vessel (i.e., a luminal axis). A monorail guidebody 22 extends distally of distal end 16 of shaft 12.



The guidebody 22 enables the device 10 to be advanced over a guidewire into the vessel through a vessel puncture and aligns a distal portion of the device 10 with the axis of vessel. As shown in Figure 11B, the Modesitt device 10 is positioned in a substantially linear blood vessel and the guide body 22 is substantially straight when the vessel closure procedure is being carried out. The guide body 22 apparently traverses a small angle bend, i.e., less than 50 degrees, when passing from a tissue tract into the blood vessel V, as is well understood in the vascular access arts.



Nowhere does Modesitt contemplate performing any sort of procedure at the heart. Although Modesitt is distinguishable on this and other grounds, Claim 27 has been amended to recite a catheter for accessing the heart *and engaging a heart valve*, comprising:

an elongate flexible body, having a proximal end and a distal end;

Appl. No. : 10/628,880  
Filed : July 28, 2003

an anchor zone on a distal portion of the flexible body the anchor zone *being configured to bend at least about 90 degrees to extend at least into an anatomical region adjoining the heart valve*; and

at least one tissue manipulator carried by the flexible body proximally of the anchor zone.

Modesitt does not teach or suggest these limitations. For example, Modesitt is clearly directed to the closure of vascular punctures, such as those achieved using the Seldinger technique. As such, the Modesitt device would be dimensionally incapable of accessing a heart valve. Indeed, needles 38 (see, e.g., Figure 5) extend the entire length of the Modesitt device between the proximal manifold and the foot 24. As disclosed by Modesitt, “needles 38 typically have a length of between about 5.0 inches and 6.0 inches ....” Column 8, lines 5-7.

Nor does Modesitt contemplate a structure configured to bend at least about 90 degrees in use. Puncture closure devices of the type disclosed in Modesitt are only required to traverse a bend in the vicinity of 35° to about 50°, to accommodate the entrance angle into the vessel achieved using conventional Seldinger access techniques. There is no disclosure in Modesitt of configuring the device disclosed therein for substantially greater flexibility, of the type required by Applicants’ claimed invention in which the catheter is configured to bend at least about 90° to extend across the mitral valve and through the left ventricular outflow tract. For at least these reasons, Modesitt does not teach or suggest Claim 27 as amended herein. Applicants respectfully request that the rejection of Claim 27 based on Modesitt be withdrawn.

Claim 31, which also was rejected as anticipated by Modesitt, depends from Claim 27 and further defines the invention thereof. Accordingly, for at least the same reasons as stated above in connection with Claim 27, the limitation of Claim 31 are not taught or suggested by Modesitt. Applicants respectfully request that the rejection of Claim 31 based on Modesitt be withdrawn.

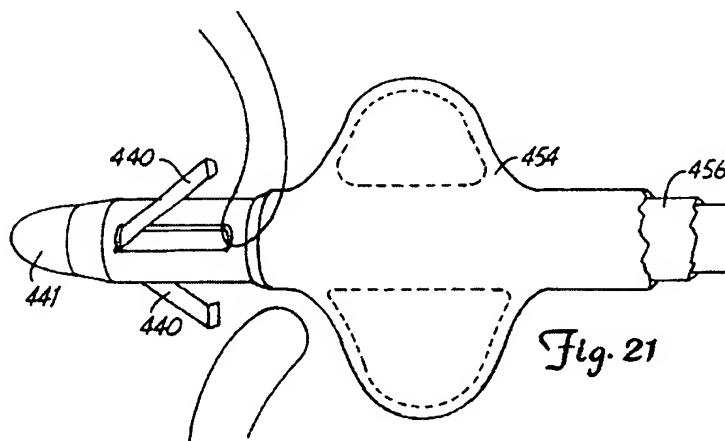
Claims 28-30, which were rejected as obvious over Modesitt alone, depend from Claim 27 and further define the invention thereof. As discussed above, amended Claim 27 is not anticipated by Modesitt. Accordingly, for at least the same reasons as stated above in connection with Claim 27, Claims 28-30 are not taught or suggested by Modesitt. Applicants respectfully request that the rejection of Claims 28-30 based on Modesitt be withdrawn.

Rejections of Claims 27 and 32-34 Based on Kuehn

Claims 27 and 32-34 have been rejected as anticipated under § 102 based on Kuehn (U.S. Patent No. 6,165,183). Applicants disagree with the characterization of Kuehn and with this rejection of Claims 27 and 32-34. However, to expedite allowance Claim 27 has been amended as set forth above. Amended Claim 27 and the claims that depend therefrom are allowable over Kuehn, as discussed further below.

**Kuehn**

Kuehn is directed to devices for heart valve repair. The examiner refers to a structure labeled with a reference number 441 as an “anchor zone on a distal portion of [a] body.” The structured labeled as 441 is actually described in Kuehn as a “grasper tube” and is illustrated as being very short compared to two graspers 440, which are described as being “less than about 10 mm in length.” Col. 10, lines 2-3. See Figure 21, reproduced below.



Applicants do not agree that the “grasper tube” in Kuehn is an anchor zone within the meaning of Claim 27 as originally filed. However, to expedite allowance, Claim 27 has been amended as set forth above. In particular, Claim 27 recites, inter alia, “an anchor zone on a distal portion of the flexible body the anchor zone being configured to bend at least about 90 degrees to extend at least into an anatomical region adjoining the heart valve.” Applicants respectfully request that the rejection of Claim 27 be withdrawn and that the examiner allow this claim. Claims 32-34 depend from Claim 27 and further defines the invention thereof. Accordingly, for at least the same reasons as stated above in connection with Claim 27, Claims 32-34 are

Appl. No. : 10/628,880  
Filed : July 28, 2003

allowable. Applicant respectfully request that the rejection of Claims 32-34 based on Kuehn be withdrawn.

#### New Claims

Applicants have added new claims 82 through 91, to further define Applicants' present invention. Claim 82 is believed to be distinguishable over the cited art for a variety of reasons. As recited therein, the catheter body is of a length sufficient to reach the heart from a femoral vein access. The device disclosed in Modesitt is expressly too short to meet this limitation, and there is no reason why one of skill in the art would modify Modesitt in this manner. In addition, there is no reason why Modesitt's guide body 22 would be sufficiently long and flexible that it can extend through the mitral valve and into the left ventricular outflow tract to stabilize a catheter while the tissue manipulator is positioned at a leaflet of the mitral valve. Kuehn fails to disclose at least an anchor zone which is sufficiently flexible and long that it can extend through the mitral valve and into the left ventricular outflow tract to stabilize the catheter while the tissue manipulator is positioned at a leaflet of the mitral valve.

#### CONCLUSION

In view of the foregoing, Applicants respectfully submit that all pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved.

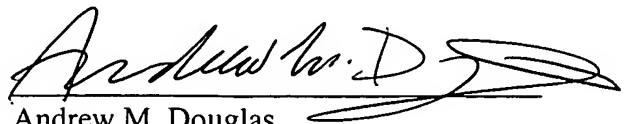
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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